

**Appl. No.** : 10/005,684  
**Filed** : November 8, 2001

### **REMARKS**

Claim 1 has been amended and new Claims 7-11 have been added. As a result, Claims 1-11 remain pending in the present application. Support for the amendments and new claims is found in the specification and claims as filed. Accordingly, the amendments do not constitute the addition of new matter. Reconsideration of the application in view of the foregoing amendments and following comments is respectfully requested.

#### Information Disclosure Statement

The Examiner stated that the information disclosure statement fails to comply with 37 C.F.R. § 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. The Examiner has placed the IDS in the application, but the information has not been considered.

The IDS filed on March 15, 2002 cited 16 references which were also enclosed. A copy of the returned postcard showing that the IDS and 16 references were received at the USPTO is enclosed herein. Applicant respectfully requests that the IDS be entered and that the references therein be considered. A copy of the IDS and 16 references are enclosed herein. The fee as set forth in 37 C.F.R. § 1.17(p) is not required because the IDS was filed before the mailing of the first Office Action.

#### Rejection of Claims under 35 U.S.C. § 112

The Examiner rejected Claims 1-6 under 35 U.S.C. § 112, second paragraph because Claim 1 recites the term "normal" which the Examiner believes is a relative term.

The term "normal" is supported by the Specification at Paragraph [0104] which states, "A normal level of antibody is defined as an average level of antibody taken from a set of healthy control individuals." Furthermore, the Specification states that "the average levels are shown as the big squares on Figures 1 and 2," for example. Accordingly, the Specification has defined the term "normal."

Accordingly, Applicant respectfully requests the Examiner to reconsider and withdraw the rejection under 35 U.S.C. § 112, second paragraph.

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Rejection of Claims under 35 U.S.C. § 102

The Examiner rejected Claims 1-6 under 35 U.S.C. § 102(e) as being anticipated by Yeaman (U.S. Patent No. 6,645,725).

Yeaman teaches a method for detecting endometriosis in patient by employing immunoassays which detect autoantibodies in a serum sample which react with Thomsen-Friedenreich antigen (Tf). In column 1, lines 33-43, Yeaman refers Tf antigen and Tf-like antigen as both being a cryptic disaccharide structure masked by sialic acid.

According to M.P.E.P. 2131, a claim is anticipated only if each and every element as set forth in the claims is found, either expressly or inherently described, in a single prior art reference.

Claim 1 has been amended to recite, *inter alia*, “a) determining a level of antibodies against a plurality of antigens for autoimmune disease and/or corresponding recombinant antigens or synthetic peptides in a sample from said patient.”

As amended, Claim 1 is not anticipated by Yeaman et al. Yeaman et al. discloses a method in which only one antigen, namely the Tf antigen, is used. Accordingly, Yeaman et al. does not disclose “determining a level of antibodies against a plurality of antigens”, as recited in Claim 1. As such, Claim 1 is novel over Yeaman et al.

Accordingly, Applicant respectfully requests the Examiner to reconsider and withdraw the rejection under 35 U.S.C. § 102.

Furthermore, the pending claims in the present application are nonobvious over Yeaman et al. Yeaman et al. does not teach or suggest the use of “determining a level of antibodies against a plurality of antigens.” Yeaman et al. sets a background to the invention as “[w]hile considerable work has been carried out in terms of measuring the incidence of these antibodies in endometriosis, reproductive diseases, and other autoimmune diseases, the nature of the epitopes involved has received scant attention.” Yeaman et al. points out that “[i]n accordance with the present invention, it has been surprisingly found that a common carbohydrate moiety is present on the different aforementioned endometrial antigens. The common carbohydrate moiety is the Thomsen-Friedenreich related antigen, Gal $\beta$ 1-3GalNAc, also referred to as Tf antigen or Tf-like antigen.” Thus, the invention of Yeaman et al. relies solely on an assay for the Tf antigen. Since Yeaman et al. focused on measuring antibodies towards a single specific antigen, one skilled in

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the art would not be motivated to test a plurality of antigens because the entire teaching of Yeaman et al. is directed to the advantages of testing a single antigen.

Accordingly, Claims 1-11 are also nonobvious over Yeaman et al.

#### New Claims

New Claims 7-11 have been added. Claims 7-11 are supported by the Specification and are directed to certain aspects of preferred embodiments. Support for Claims 7 and 8 can be found in the Specification at Paragraph [0041]. Support for Claim 9 can be found in the Specification at Paragraph [0054]. Support for Claims 10 and 11 can be found in the Specification at Paragraph [0093].

#### CONCLUSION

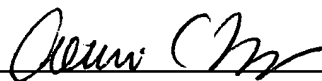
In view of the foregoing amendments and comments, it is respectfully submitted that the present application is fully in condition for allowance, and such action is earnestly solicited.

The undersigned has made a good faith effort to respond to all of the rejections in the case and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully invited to call the undersigned in order to resolve such issue promptly.

Respectfully submitted,

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Dated: April 2, 2004

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AMEND  
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